

From: [Jorge Bohorquez](#)
To: [Lancellotti, Romina](#)
Subject: RE: Healthcare Environmental Services, LLC. EPA ID FLR000234641 -Exit Interview
Date: Friday, September 4, 2020 1:32:37 PM
Attachments: [HES Diposal of Pharmaceutical Waste SOP 02012020.pdf](#)
Importance: High

Hi Romina,

Hope all is well, please find enclosed item number 2.

Regards,

Jorge L. Bohorquez
305-436-0422
www.hesmedwaste.com

From: Lancellotti, Romina <Romina.Lancellotti@FloridaDEP.gov>
Sent: Friday, August 21, 2020 5:25 PM
To: Jorge Bohorquez <jlb@hesmedwaste.com>
Subject: Healthcare Environmental Services, LLC. EPA ID FLR000234641 -Exit Interview

Good Afternoon Mr. Bohorquez,

This email serves as an exit interview to the routine hazardous waste inspection conducted by the Florida Department of Environmental Protection (FDEP) on August 19th, 2020. Thank you again for your time and assistance throughout the inspection. As discussed during the inspection, the facility shall submit the following documentation to the Department for review:

1. Hazardous waste pharmaceutical shipping records (including uniform HW manifests, bill of lading) for the last 3 years. Please provide at least 2 samples of each month for:
 - January, February, March 2020
 - January, February, March, July, August, and September 2018 & 2019.
 - July, August, and September 2017

For your reference, according to 40 CFR 263.22(a), a transporter of hazardous waste must keep a copy of the manifest signed by the generator, himself, and the next designated transporter or the owner or operator of the designated facility for a period of three years from the date the hazardous waste was accepted by the initial transporter.

2. Standard Operating Procedures (SOP) documentation describing the facility's response plan pertaining hazardous waste pharmaceutical discharges and spills (40 CFR 263.30 and 263.31).
3. Employee training in hazardous waste management and emergency

procedures.

4. Picture of the front and side of the trucks used for transporting hazardous waste pharmaceutical (with placards and DOT number)
5. Screenshot of waste profiles.

Please provide a response and evidence of your corrective actions by **September 4th, 2020**. Please do not hesitate to reach out to myself if you have any questions or concerns.

Best Regards,



Romina Lancellotti

Environmental Specialist II

Florida Department of Environmental Protection

Southeast District – West Palm Beach

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[Dep Customer Survey](#)





Hazardous Waste Pharmaceuticals SOP Response Plan Pertaining Hazardous Waste Pharmaceutical Discharges and Spills

FEBRUARY 1, 2020



HAZARDOUS PHARMACEUTICAL WASTE SOP

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I. PURPOSE

The purpose of this Hazardous Pharmaceutical Waste Operating Plan is to provide guidance and describe requirements for the proper management of Hazardous Pharmaceutical Waste in our facility, during transportation and discharges. **Healthcare Environmental Services (HES)** is committed to full compliance with federal, state, and local laws and regulations pertaining to the management of Pharmaceutical Hazardous Waste. Guidelines for management of Transporters of Hazardous Waste are found in Section 62-730.170, Florida Administrative Code (F.A.C.), and in 40 CFR 263.30 and 40 CFR 263.31.

II. KEY DEFINITIONS

Pharmaceutical means

- Any drug or dietary supplement for use by humans or other animals
- Any electronic nicotine delivery system (ENDS)
 - e.g., electronic cigarette or vaping pen
- Any liquid nicotine/e-liquid packages for retail sale for use in electronic nicotine delivery systems
 - e.g., pre-filled cartridges or vials

Hazardous waste pharmaceutical means

- A pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D.
- A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (*e.g.*, lawfully donated for its intended purpose) or reclaimed.
- An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (*e.g.*, lawfully redistributed for its intended purpose) or reclaimed.

Healthcare facility means

- Any person that is lawfully authorized to—
 - (1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or
 - (2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.



- This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals.
- This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Potentially creditable hazardous waste pharmaceutical means

- A prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit or a nonprescription hazardous waste pharmaceutical that has a reasonable expectation to be legitimately used/reused or reclaimed, and is—
 - (1) In original manufacturer packaging (except pharmaceuticals that were subject to a recall)
 - (2) Undispensed; and,
 - (3) Unexpired or less than one year past expiration date. The term includes, nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

Non-creditable hazardous waste pharmaceutical means

- A prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed.
- This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

Non-hazardous waste pharmaceutical means

- A pharmaceutical that is a solid waste, as defined in § 261.2, and is not listed in [40 CFR part 261](#) subpart D, and does not exhibit a characteristic identified in [40 CFR part 261](#) subpart C.

**Non-pharmaceutical hazardous waste means**

- A solid waste, as defined in § 261.2, that is listed in [40 CFR part 261](#) subpart D, or exhibits one or more characteristics identified in [40 CFR part 261](#) subpart C, but is not a pharmaceutical, as defined above.
- Unexpired or less than one year past expiration date. The term includes, nonprescription pharmaceuticals including, but not limited to, over the counter drugs, homeopathic drugs, and dietary supplements and clean-up material from the spills of pharmaceuticals.

Reverse distributor means

- Any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit.
- Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

Reverse logistics means

- A facility that receives nonprescription pharmaceuticals that have a reasonable expectation of being legitimately used/reused or reclaimed in order to capture some value or serve an intended purpose.
- Such products are not considered solid waste or hazardous waste.

Very Small Quantity Generator means

- A site that generates less than or equal to 1 kg (2.2 lbs.) of acutely hazardous waste, including acutely hazardous waste pharmaceuticals, in a calendar month.
- A site that generates less than or equal to 100 kg (220 lbs.) of hazardous waste, including hazardous waste pharmaceuticals, in a calendar month.

Strictly speaking, the HWP rule only applies to hazardous waste pharmaceuticals; however, all generators of waste pharmaceuticals are strongly encouraged to manage both “hazardous waste pharmaceuticals” and “non-hazardous waste pharmaceuticals” as HWP. **The only time non-hazardous waste pharmaceuticals are not required to be managed/disposed as HWP is when a documented waste determination has been made confirming the waste pharmaceutical is not a hazardous waste pharmaceutical.**



Additionally, sites that are considered Very Small Quantity Generators (VSQGs) of hazardous waste/HWP are not regulated under the HWP rule, but are allowed to send potentially creditable HWP to reverse distributors, and must abide by the HWP sewer ban as well as the HWP rules for empty containers.

Pharmaceutical wastes must not be discharged to the sanitary sewer or disposed in the regular trash unless a waste determination has indicated they are non-hazardous. Pharmaceutical wastes that have a reasonable expectation of legitimate use/reuse (e.g., lawful donation or redistribution for their intended purposes) or reclamation are not hazardous waste pharmaceuticals. However, if these pharmaceuticals are not ultimately used, reused, or reclaimed, the pharmaceuticals shall be managed as Non-Creditable HWP unless a waste determination has indicated they are non-hazardous.

III. HAZARDOUS PHARMACEUTICAL WASTE COLLECTION PROCEDURES

a) Segregation

All Pharmaceutical Waste stored together must be compatible. Incompatible waste (biomedical waste, for example) generated by a Biomedical Waste Generator should be separated by storing these wastes in separate cabinets or shelves. Mixing of wastes that represent different hazard classes must be avoided.

b) Packaging and Containers

Hazardous waste must be collected by generators in containers that meet Department of Transportation (DOT) specifications. The same container or type of container in which a reagent was shipped will meet the specifications for shipment as waste. It is imperative for the safety of the HES employee that correct labeling is applied to the Pharmaceutical Waste container. Keep containers closed. All Hazardous Pharmaceutical waste containers must be kept closed except when being used for the addition or removal of wastes. One of the most common cited safety hazards is open containers and labeling deficiencies.

c) Labeling

Each container must be labeled according to the EPA/DOT guidelines. Pharmaceutical Hazardous Waste must include the word **Hazardous Waste** on the label.

d) Inspection

Generators must inspect their accumulation areas to make sure that collection containers are clean, closed, properly labeled, segregated, and not leaking.



e) Initiating Waste Removal by the Generator

To request a Hazardous Pharmaceutical Waste pick up, the generator must contact **HES** at **305.436.0422**. **HES** must approve a waste profile provided by the Generator for each generator facility prior to scheduling a pickup. **HES** must provide a Hazardous Waste Manifest to the Generator when conducting a pickup. The Generator coordinates the removal of Hazardous Waste from their facility at a minimum every 180 days, or as needed. In the event the generator status increases from a small to a large quantity generator the frequency of disposal will increase to a minimum 90-day interval. HES will deliver the Hazardous Pharmaceutical Waste to Triumvirate, HES does not store the Hazardous Pharmaceutical Waste within its premises.

IV. EMPLOYEE INFORMATION AND TRAINING

- a)** All employees involved in any aspect of the handling and transportation of Hazardous Pharmaceutical Waste, must receive training that covers the following:
 - Overview of **HES** Hazardous Pharmaceutical Waste program.
 - Description of the health hazards associated with exposure to hazardous drugs,
 - Signs and symptoms of exposure.
 - Instructions on how to report any signs or symptoms that may be attributable to hazardous drug exposure.
 - Work practices to reduce exposure, including engineering controls and Personal Protective Equipment required.
 - Instructions for handling spills and emergency procedures.
- b)** The Hazardous Communication training part of the OSHA Standard must be conducted at least annually or whenever a new hazard is introduced into the work area or the employee demonstrates behavior that indicates a lack of understanding of the safe handling of hazardous drugs.
- c)** Supervisors are responsible for ensuring that employees with potential exposure to hazardous drugs receive the appropriate training prior handling and transporting Hazardous Pharmaceutical Waste.
- d)** All training must be documented by the individual presenting the training session, and a copy of the training records will be for a minimum of three (3) years.
- e)** HES Healthcare Facility personnel who dispose of HWP must complete Hazardous Waste Pharmaceutical Disposal Training annually as part of the EPA and DOT.



Training must be completed in-person and HES must retain training records for all personnel who transport and dispose of HWP.

V. PROCEDURE FOR PHARMACEUTICAL WASTE SPILLS

HES must ensure there are adequate spill kit(s) available to immediately respond to pharmaceutical spills. All pharmaceutical spills will be managed and disposed as hazardous pharmaceutical waste unless a waste determination has been conducted and the spilled material has been deemed non-hazardous.

Recommended spill kit contents include:

- Personal Protective Equipment to be used “only” for spill cleanup
- Disposable gloves, lab coat/apron, and shoe covers
- Splash goggles
- Small plastic dustpan and brush
- Small plastic container for broken glass
- Vermiculite, clay, cellulose, or amorphous alumina silicate adsorbent(s)
- Adsorbent towels, pads, and/or mats
- Heavy duty (3 mil) polypropylene bags
- Pail or other container to hold kit contents

VI. IMMEDIATE ACTION

In the event of a discharge of hazardous waste during transportation, HES must take appropriate immediate action to protect human health and the environment (e.g. notify local authorities).

If a discharge of hazardous waste occurs during the transportation and an official (State or local government or a Federal Agency) acting within the scope of his official responsibilities determines that immediate removal of the waste is necessary to protect human health or the environment, that official may authorize the removal of the waste by transporters who do not have EPA identification numbers without the preparation of a manifest.

An air, rail, highway, or water transporter who has discharged hazardous waste must:

1. Give notice, if required by 49 CFR 171.15 to the National Response Center (800-424-8802 or 202-426-426-2675); and
2. Report in writing as required by 49 CFR 171.16 to the Director, Office of Hazardous Materials Regulations, Materials Transportation Bureau, Department of Transportation, Washington, DC 20590

A water (bulk shipment) transporter who has discharged hazardous waste must give the same notice as required by 33 CFR 153.203 for oil and hazardous substances.



VII. DISCHARGE CLEAN UP

HES must clean up any hazardous waste discharge that occurs during transportation or take such action as may be required no longer presents a hazard to human health or the environment.

VIII. TRANSPORT

HES will negotiate the transport of Hazardous Pharmaceutical Waste exclusively with EPA registered companies. We will have on file the pick-up receipts for the last three (3) years. Transport for our facility is provided by:

Triumvirate 10100 Rocket Blvd.

Orlando, FL 32824

407-859-4441

US EPA ID NUMBER FLR981018773

IX. CONTINGENCY PLAN

If our registered Pharmaceutical Waste Transporter is unable to provide services the following registered Hazardous Pharmaceutical Waste Transporter will be contacted:

Trilogy Medwaste SE – Pompano

Clean Earth

492 Webster Chapel Rd.

Glencoe, AL 35905

256-492-8340

US EPA ID NUMBER ALD981020894